

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0508]

dmb

Received	1-6-08
Reviewed	1-9-08
by	<i>J. Cooke</i>

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey of Healthcare Practitioners Regarding Their Preferences for Public Health Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a survey of healthcare practitioners' preferences regarding public health notifications (PHNs).

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Survey of Healthcare Practitioners Regarding Their Preferences for PHNs

The PHN is one of the tools that the Center for Devices and Radiological Health (CDRH) uses to get an important message to the user community about risks associated with use of medical devices. This particular tool is meant to serve a specific purpose not served by the other communication tools at our disposal—to be a source of information for healthcare practitioners, immediately recognizable as a statement from FDA, about a device risk with information on how to avoid or mitigate the risk. The purpose of this project is to evaluate the current notification format and distribution process for CDRH, with the goal of determining what is necessary to assure that the notifications reach, and are acted upon by, the target audience. The center needs to know that it is using the most effective approach to formatting and to disseminating PHNs to assure that they are received, recognized, understood, and acted upon quickly and effectively by medical practitioners and institutions. Considerations include, but are not limited to, design, terminology, nomenclature, distribution, utility of standardization, relationship with other medical product notifications (e.g., recalls), use of electronic transmission, and use of plain language.

The intent of this project is to determine the preferences of the healthcare community for learning from FDA about risks associated with medical devices and to compare the current process against the approach identified by the research to be “preferred” with the intent of improving our format and process.

CDRH will conduct a survey of a sample of healthcare providers who receive a new PHN from FDA. Most recently, FDA has been using intermediary organizations, such as professional associations, to help us distribute notifications to the appropriate target audiences and we are assuming that any

new PHN will be disseminated in this way, using the appropriate association to distribute the PHN to their members. Generally, the PHN is distributed to the target audience electronically, either as a link embedded in a news article or sent directly via e-mail from either the professional association or FDA using the e-mail listing provided by the professional association. As part of the notification, we will provide a link to a Web-based questionnaire that will collect information related to the healthcare providers' preferences for learning about risks associated with medical devices.

The information collected in this survey will help FDA identify the most effective format(s) and distribution method(s) for CDRH PHNs.

FDA estimates the burden of this collection of information as follows:

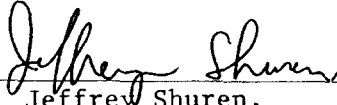
TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Survey of healthcare providers in relevant specialty	300	1	300	.1666	50
Survey of healthcare providers in another relevant specialty	300	1	300	1666	50
Total					100

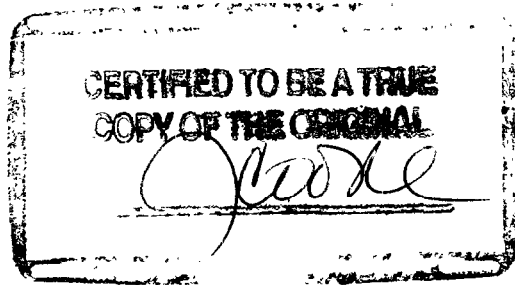
¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions and completing the questionnaire.

Dated: **JAN 03 2006**
January 3, 2006.



Jeffrey Shuren,
Assistant Commissioner for Policy.



[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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